

AMENDMENTS TO THE SPECIFICATION

The Applicant notes that the Examiner has commented on the introduction of new material in the Applicant's 9/24/3003 amendment. Since the Applicant has withdrawn the 9/24/03 amendment these specific objections are addressed.

The Applicant has carefully examined the original specification and has been careful not to introduce any new material with the amendments herein. The Applicant has marked up the original specification in accordance with 37 CFR 1.125 guidelines. The Applicant's amendments to the specification are to correct grammatical issues, to more clearly define the art described in narrative terms without introducing new material, and to use clearer patent prosecution language in accordance with patent law and procedures.

It should be noted in the Examiners response that the Examiner made specific references to the Applicant adding new material related to the Internet for data transmission to and from the Bodily Worn device. The Applicant respectfully disagrees with these comments respectfully points to numerous references to the Internet in the original specification including: Summary of the Invention, paragraph 4...."interface box which could be used to modem information into the Bodily worn device from a remote location." In addition, numerous the original specification has numerous references to wireless or telecommunication links between the Bodily worn device and the handheld unit and the Base unit. Therefore, the amendments to the specification presented herein are valid and do not introduce any new material to the specification and application.

Amendments to the Specification:

Background of the Invention

Simple bodily worn medical bracelets and medallions have been used for many years by individuals with serious medical conditions to alert emergency medical personnel in the event the wearer is stricken and -unconscious that the wearer has a serious pre-existing medical condition which requires special medical treatment. Although these simple bracelets and pendants have been useful they lack the space and storage capacity necessary to hold critical lifesaving -medical information and any electronics to interface with modern patient monitors and or electronics. Such critical lifesaving information includes: blood type, a description of pre-existing medical conditions, photo ID or other positive identification, ECG scan, Cardiac, Ultrasound scan, present drug usage and interaction cautions, severe drug and other allergic reactions. The invention disclosed herein, and complimentary inventions disclosed by the inventor, teach the design of bodily worn or carried devices which can store large amounts of digital medical records and have those records retrieved in a rapid wireless or contact manner in the event of a medical emergency. The Bodily Worn Device (BWD) can also be embodied into a digital storage card and/or medical computer disk, which is disclosed in another invention by this inventor. Also, other key medical and personal information which can be stored into the bodily worn digital devices include Organ Donor Instructions and Living will instructions which have become very common place and vital to the medical community as well as the individual. Integral to the use of the Bodily worn digital storage devices (BWD) are the inventions disclosed herein which are medical monitors, personal computers, portable display devices and interface electronics used to organize medical records, ~~as an option~~ encrypt the records for security, transmit the records through

interface electronics and ~~"burn-in"~~ digitally write the data on computer chips and other suitable storage media located within and part of the BWD. There are a plurality of possible hardware, communications and software configurations for the invention herein. ~~There are s~~ Several of a plurality of embodiments of the invention are disclosed herein, which will most likely be the most convenient and usable commercial versions of the invention.

By disclosing these possible embodiments the inventor is by no means limiting the scope of the invention to said embodiments and the inventor claims the broadest interpretation of said plurality of embodiments. These include: 1. a portable field unit which will include a display screen, microcomputer, interface wand, software, and a means of transmitting data back to a base unit in an emergency 2. an interface module which, in lieu of an entire new patient monitor, can be added to a IU slot in an existing patient monitor and add the capability of accepting data from the Interface Wand and BWD without adding a lot of additional cost to the health care system, 3. a more substantial Base Unit which would be most likely a PC based system and include software for organizing and editing medical data and records, ~~as an option~~ encrypting those records for confidentiality and security, and sending those records directly through the Interface Wand to be ~~"burned-in"~~ digitally written and stored within the BWD in digital storage media such as a computer chip. Although there are many "canned" existing and "off the shelf software packages currently available there is none which would allow for a concise, highly organized and standard format for displaying of emergency medical records. Since time is of the essence and correct treatment and medical intervention is often a life or death situation it is essential to have the stored medical records in a highly organized, concise standard format so an EMT can go right to the critical information, assess the best medical treatment options and act

accordingly. This highlights the need for unique software to organize the emergency medical records and information into concise and edited format for easy use and such software is disclosed herein as part of this invention.

There has been prior art in the medical industry which, although peripherally related to medical records and computer systems, does not teach the art or devices described herein. Doue in 5,361, 202 teaches a computer system and software specifically for the purpose of managing a patients stay in a hospital or clinic. Doue makes no mention of organizing or applying any critical emergency medical information, makes no mention of using or interfacing with Bodily Worn Devices or Medical cards and in general Doue's invention in no way completes with the invention disclosed herein. Since the invention disclosed herein is not used in any way, and makes no claims to manage the time frame for a patients stay in a hospital, these two patents really have nothing more in common than the fact that they use a screen and a microprocessor. Whalen in 5,327,341 teaches a computer system and software for managing general medical records and files in a hospital and physician office environment. Whalen focuses on the software side of his invention and teaches means of creating headers and organization categories for large amounts of medical information. No where in his invention does Whalen teach organizing Emergency Medical information for emergency medical treatment which is created for the purpose of storage on Bodily Worn and/ or Digital Storage cards or disks. Nowhere does Whalen teach any of the Interface Wand, Interface module and data transmission features of the devices disclosed in this invention. The main claims of the Whalen patent deal with managing and updating an individuals medical records in a routine office based setting using key words, hybrid data fields ,etc., which this invention is not claiming and for applications this invention

has no intention of addressing. Eberhardt in 5, 659, 741 teaches a medical history computer system for recording medical histories aimed at organizing very large amounts of medical data for organizations such as the federal government for keeping track of medicare and medicaid and/or for large insurance companies. This differs from the invention disclosed in that the emergency medical data described herein is not stored in a central computer but is organized and stored on Bodily Worn devices. The inventions described herein are patient monitors and interface hardware specifically aimed at retrieving and displaying the stored emergency medical data . Eberhardt fails to teach any of the patient monitors, modules or interface electronic hardware necessary to make the retrieval of emergency medical data a practical device. Although Ebehardt mentions cards or disks to carry medical records he fails to teach any type of practical card or disk and fails to teach how such a card or disk would be interfaced with a practical computer system or its components. An integral part of Ebehardt's inventions, which is not required by the invention disclosed herein, is the ability to sort for medical information and/or data by key word, phrase, etc.. This is not necessary for the invention described herein in terms of its software and is outside of the scope of this invention.

Summary of the Invention

The invention disclosed herein has describes several of a plurality of possible different embodiments of the invention and its hardware and software configurations. These descriptions are in no way meant to restrict the scope and broadness of the possible embodiments of the invention and it is acknowledged that other embodiments, other

than the preferred embodiments described, may be appropriate for use and are incorporated herein. ~~described in the Background narrative. What all of these embodiments have in common is:~~ One of a plurality of preferred embodiments may include:

-interface hardware and electronics, embodied in the form of the Interface Wand and module IO card, for electrically powering and retrieving the data from the bodily worn devices in a wireless, non -contact fashion

-software which is compatible with the software and organization platform of the Bodily Worn devices for retrieving, organizing and displaying the stored records in rapid format for emergency situations.

-some form of a screen display which could include an LCD screen, video screen, cathode ray tube, or computer screen for displaying the records in emergency situations.

-a means of periodically updating the records stored on the Bodily worn devices by interfacing the Bodily worn device with the monitors, either using the Interface wand and a direct connection to a monitor or via the wand and an interface box which could be used to modem information into the Bodily Worn device from a remote location: using the Internet, Intranet, Wi-Fi, or a plurality of other modem and telecommunications media. Said modem may be used to link the system to the Internet and a website for two way data transmission.

~~-As an option but not a requirement-~~ a means, through unique software encryption and recognition techniques, to interface with unique smart cards and/ or unique computer disks which have permanently imbedded software security identification markers. This type of a marker and recognition system allows for only authorized types of disks and card, which have the unique embedded digital markers, to be used and recognized by the system software for security and anti fraud purposes. The alternative, which is an embodiment of this invention, is to have an open architecture software

-smart software and two way data transmission between the interface hardware and the Bodily Worn devices and cards and disks. This smart software allows for recognition of encrypted security markers to eliminate unauthorized entry to the devices and well as for anti fraud purposes during data transmission.

-electronic cases and enclosures which make the devices herein either rugged and portable for field use and/or military use, enclosures and electronic covers for the module Interface to safely add the module and upgrade to an existing patient monitor, or an enclosure for making the devices desk top and fairly stationary for use in an office environment.

Detailed Description of the Invention

Reference Figure 1

Figure 1 represents a flow chart of how the integral hardware components of the system would interface. Either the portable field unit, patient monitor module or base unit

monitor can send or retrieve data from the Bodily Worn Devices (BWD) via the Interface Wand. Or docking port of figure 6. In turn, either the Portable Field Unit or the Patient Monitor Module can also send data to and from the Base Unit Monitor via either telephone lines, wireless AM or FM transmission, said modem, or a plurality of other communications media described herein. ~~any other appropriate transmission means.~~ The interface wand, and docking station of figure 6, is an integral part of the system for sending and retrieving data from the BWD. The Interface Wand has a means of simultaneously sending electrical power to the BWD via, a plurality of -wireless mediums including inductance means while at the same time sending and retrieving data from the BWD via, a plurality of medium, including either optical, or capacitance data transmission. ~~The detailed disclosure of the art of the Interface Wand and BWD are covered in another US patent filing by this inventor (reference US xxxx).~~ The transmission of data to and from the Bodily worn device can be accomplished via a plurality of contact means via the interface wand or by directly docking or porting the bodily worn storage device to the portable reader or base unit via an existing computer port. As previously described the portable field unit and the Base unit Monitor both have the electronics to receive and transmit data to and from the Interface Wand, to display medical data on a screen for Emergency Medical treatment , and to send the data wireless or over telephone lines, including said modem, to other stations. The use of said modem and its link to the Internet can also allow for bi-directional transmission of data from an Internet website to the Bodily worn device. The patient monitor module, which is an electronic card which fits into an existing patient monitor, is described in more detail in figure 5. Common software allows the devices disclosed herein to communicate, send and retrieve data and encrypt data in secure means for confidentiality and security.

Reference Figure 2

Figure 2 shows a schematic of the system operating software and its flow in terms control and organization of data transmission through the various pieces of hardware in the system. Two-way data transmission is important through each piece of hardware to allow for medical data and records to be both sent and retrieved through the Interface Wand and into and out of the BWD. As shown in figure 4 Emergency Medical Records are organized by the software into pages or files with discrete information organized in sections or blocks to create a standard page. The pages are prioritized based on a combination of factors including: clinical relevance in an emergency, chronological order, and a patients pre-existing medical conditions and their relative risks in a medical emergency. This standard page is important in that because in the event of a medical emergency, where time is critical, and if a standard page format allows is created for EMT's and technicians then they to know exactly where to look to get critical life saving information without searching. The software is organized as such so that Emergency Medical records are created for a patient either from the Base Unit, Portable Field Unit or Ambulatory Patient Monitor, but most preferably in the Base Unit. The Patient files are encrypted to provide for security during transmission over said modem, telephone, and/or data lines. The software is organized as such so the patient files d are transferred through the Interface Unit or Wand into the BWD in file or page format. These patient files are organized through the software into a plurality of standard software formats including generic ASCII type files so as the be retrievable and readable using standard software packages in conjunction with our the unique ~~decryption~~ encryption software described herein. As an alternative and/or enhancement to the encrypting of the medical files security software markers could be written into the

medical record files so that only persons with compatible software, which can recognize the security markers, would be allowed to retrieve and open the medical records stored on the system Bodily Worn devices BWD's or on system electronic cards or disks described herein.

Reference figure 3

Figure 3 shows ~~one variation of how all~~ is a graphic representation of one of a plurality of possible hardware configurations of the the system. Figure 3 depicts how ~~of the main~~ components of the system function in relation to each other ~~work~~ including: the Bodily Worn Device, Interface Wand, Portable field unit, Base unit and controlling software. When the wearer of the BWD is stricken with any illness, or is in an accident, or injured in combat etc. an EMT, paramedic, or military corpsman ~~etc.,~~ can access the critical medical data using the portable field unit, assess the stricken persons overall condition using the pre-existing medical history and data in the BWD, and rapidly determine the best coarse of medical treatment, which could prove life saving. The portable field unit has the ability to transmit medical data and treatment options to the base unit, ~~and visa versa~~ in a bi-directional manner, so hospital based medical personnel can communicate directly with the field paramedic via a plurality of media including said modem, wirless communications, or other wireless or hardwired telecommunications media.

An integral part of this invention is the design and ~~inter-related working mechanism~~ electro-mechanical interface between the BWD, storage cards and storage disks. This is expanded on in figure 6 of this invention.

Reference figure 4

figure 4 shows one typical of a plurality of possible software configurations for the Emergency Medical Record organization. The medical data can either be in file or page format with discrete blocks or sections of a page devoted to specific information so as to create a standard and easily recognizable format in an emergency situation. Menus or point and click software commands can be set up so as to allow the user to rapidly scroll through pages to find information. As previously described said pages and data fields are organized based on a plurality of factors including: relevance and utility in a medical emergency, chronological order, and a users pre-existing medical condition and the relative risk of said conditions in a medical emergency.

Reference Figure 5

figure 5 shows one typical of a plurality of possible configurations for the hardware module, which would be used in conjunction with an plurality of existing patient monitors including: in an ambulance monitor, emergency room monitor, and portable monitor, etc. The plug-in module depicted in figure 5 is one of a plurality of configurations including: consists of a faceplate with controls, switches etc. for on/off power, data transmission indicator lights, power indicator light and any other appropriate controls and indicator lights. An I/O type printed circuit card is mounted to the faceplate and all electronic components and circuitry are mounted to the pc board. The electronic circuitry to supply power to the board, as well the circuitry which routes the data signals through the card, are routed to electronic contact pads or fingers as, they are known in the industry. The pads are either silver or gold plated and allow the pc board to be

plugged into the mating slot in the said patient monitor so as to accept electrical power from the said patient monitor and allow said medical records and data to be transmitted and received through the pc board and its connecting pads. As previously described the data cable connects the Interface wand to the front panel of the module. The cable allows data to be transmitted from and sent to the Bodily worn devices using either fiber optic, USB, or serial or parallel two-way data transmission.

Reference Figure 6

~~As previously mentioned, t~~ The design and working mechanism of the Interface wand, as it relates to Bodily Worn Device or Card or Disk, ~~is critical~~ significant as one of a plurality of embodiments to access data within this electronic system. The two devices and their working mechanisms as described herein are unique and novel. This inventor has also written and submitted a separate patent on the Digital Card and Disk and mechanisms to read and transmit data. Figure 6 shows three typical embodiments of this invention and ~~this is not to say~~ it is noted that more embodiments do not ~~may~~ exist which are part of this invention and are incorporated herein. The Interface wand is designed in one of a multitude of Embodiments including:

a) ~~to include~~ a housing, electrical power pads to supply power to the BWD via inductance or other contact or non-contact means , data transmission and retrieval capacitance pads to allow bi-directional flow of digital data in a contact or non-contact manner, a means of aligning the wand and BWD so as to make positive mechanical alignment between the power and data pads.

Embodiment b) shows an alternative design of the Wand whereby a case or slot enclosure in the form of a docking station or port will allow either the BWD, a card or disk to be inserted into the slot. The power pads and data transmission pads are mounted on the interior wall of the enclosure so as to provide protection in the event the wand is dropped or hit. The slot enclosure docking station and BWD, card, disk are designed so the electrical power pads and data pads make proper alignment when the BWD is inserted and hits a mechanical stop in the slot. Data and electrical power can be transmitted in either a contact or non-contact manner.

Embodiment c) shows a wand with a mechanical slot in the form of a port of docking station for insertion of a storage disk or card. In this embodiment only an optical read/write pad is required utilized, which is one of a plurality of possible embodiments of data exchange. ~~Since~~ The digital data is stored on an optical film or polymer on the surface of the disk or card, in a similar manner as a compact disk. This data storage embodiment may provide either that neither the wand nor disk require any power to retrieve the digital information from the disk. ~~It should be noted that~~ Electrical Power is required to be sent to the optical scanner in the wand so as to power its operation. The bi-directional reading and writing of data to and from the disk or card can be accomplished with a plurality of optical scanner / writer pads mounted to the inside of the wand.